

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC. and AMGEN
MANUFACTURING, LIMITED,

Plaintiffs,

v.

HOSPIRA, INC. and PFIZER INC.,

Defendants.

C.A. No. 18-1064-CFC

PUBLIC VERSION

Filed December 10, 2019

**DEFENDANTS' LETTER BRIEF IN SUPPORT OF THEIR
MOTION TO STRIKE PORTIONS OF PLAINTIFFS' INFRINGEMENT
CONTENTIONS REGARDING U.S. PATENT NO. 9,643,997 AND
EXPERT REPORTS APPLYING A NEW CLAIM CONSTRUCTION**

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*Attorneys for Pfizer Inc. and
Hospira, Inc.*

Dated: December 3, 2019

Dear Judge Connolly:

Defendants Hospira, Inc. and Pfizer Inc. request that the Court preclude Plaintiffs Amgen Inc. and Amgen Manufacturing, Limited and their experts, Drs. Zydney and Sullivan, from relying on a newly proposed construction for the claim phrase “applying the refold solution to a separation matrix” in claim 9 of Amgen’s U.S. Patent No. 9,643,997 (“the ’997 Patent”) that materially differs from the agreed construction reached over ten months ago, prior to the claim construction hearing in this case.

The parties exchanged preliminary lists of claim terms on January 25, 2019 and as a result agreed that “applying the refold solution to a separation matrix” means “applying the refold solution to a separation matrix without intervening steps of dilution, centrifugation, dialysis, or precipitation.” Ex. 1 at 2; Ex. 2. The exclusion of the four intervening steps reflected Amgen’s surrender during prosecution of dialysis, precipitation, and centrifugation to overcome a rejection based on the prior-art Oliner reference and the explicit disclaimer in the specification of the ’997 Patent that it “excludes the step of dilution.” Ex. 3, Patent Owner’s Preliminary Response in IPR2019-00797 concerning the ’997 Patent at 20-21; Ex. 4, Oliner at col.76, ll.51-57. The parties represented to the Court that they had reached agreement on the meaning of this phrase in their Joint Claim Construction Brief filed on April 22, 2019. Ex. 5, D.I. 55 at 25.

On October 11, 2019, Amgen served supplemental infringement contentions where, for the first time, Amgen proposed the definition below for the “applying” claim phrase:

applying the refold solution to a separation matrix without intervening steps of dilution, centrifugation, dialysis, or precipitation, **as practiced in the prior art—e.g., Wang, et al., Biochem. J., 325:707-710 (1997), which calls for dilution of approximately 25 fold, and U.S. Patent No. 7,138,370 (“Oliner”), which employs dialysis, followed by acid precipitation requiring centrifugation to remove the precipitate.**

Ex. 6 at 8 (citations omitted) (emphasis added). The parties’ agreed-to construction did not contain the qualifying language bolded above.

Pfizer does not agree with Amgen’s new construction and it materially changes the scope of the claim. Amgen’s new construction, if it had been timely presented, would have been disputed and briefed so that it could have been construed by the Court. While the parties’ agreed-to construction excluded the intervening step of “dilution,” Amgen’s new construction tethers the meaning of

"dilution" to a single prior-art reference (Wang) that allegedly requires "a dilution of approximately 25 fold." Ex. 6 at 8. Similarly, while the agreed-to construction excluded "precipitation," Amgen's new construction excludes only one particular type of precipitation, namely "acid precipitation." *Id.* And where the agreed-to construction excluded the intervening steps of centrifugation, dialysis, **or** precipitation, Amgen's new construction excludes only "dialysis, **followed by** acid precipitation requiring centrifugation to remove the precipitate." *Id.* (emphasis added). Amgen's new construction therefore requires that dialysis, **acid** precipitation, and centrifugation occur in the sequence that those steps were performed in the Oliner reference in order for those steps to fall outside the scope of the '997 Patent. Amgen's new construction in essence eviscerates the exclusion from the method of claim 9 the four intervening steps of the agreed-to construction.

Amgen's opening expert reports are predicated on Amgen's new construction. Instead of opining on whether Pfizer's process incorporates intervening dilution, dialysis, or precipitation steps under the agreed construction, Amgen's experts, relying on the new construction, [REDACTED]

[REDACTED] Amgen's experts should not be permitted to shoehorn a new claim construction into this case under the guise of expert discovery. In Exhibits 7 and 8, Pfizer highlights the portions of these reports that should be stricken.

Amgen's motivation for abandoning the parties' agreed construction of the "applying" step is clear. [REDACTED]

[REDACTED] Amgen's attempt to narrow the scope of the disclaimed steps is not only untimely, but it is

also contrary to basic claim construction principles that must take into account disclaimers and disavowals made to obtain the patent. *Std. Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 452 (Fed. Cir. 1985) (“Thus, the prosecution history (or file wrapper) limits the interpretations of claims so as to exclude any interpretation of claims that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance.”). The scope of a surrender of subject matter during prosecution is not limited to what was absolutely necessary to avoid a prior-art reference that was the basis for an examiner’s rejection. *Norian Corp. v. Stryker Corp.*, 432 F.3d 1356, 1361 (Fed. Cir. 2005). Rather, “it frequently happens that patentees surrender more through amendment than may have been absolutely necessary to avoid particular prior art.” *Id.* In those circumstances, the Federal Circuit has “held the patentees to the scope of what they ultimately claim, and we have not allowed them to assert that claims should be interpreted as if they had surrendered only what they had to.” *Id.* at 1361-62.

Pfizer will be prejudiced if Amgen is permitted to pursue an infringement theory predicated on a construction that departs from the agreed-to construction. Pfizer identified prior art, developed invalidity contentions, and sought discovery based, in part, on the understanding that the parties agreed that the “applying” phrase excluded the intervening steps of “dilution, centrifugation, dialysis, or precipitation” without the additional qualifying language that Amgen now proposes. When Pfizer attempted to probe Amgen’s understanding of the meaning of the phrases dilution, dialysis, and precipitation during the August deposition of Amgen’s 30(b)(6) witness on the prosecution of the ’997 Patent, [REDACTED]

[REDACTED] To alleviate the prejudice caused by Amgen’s newly proposed construction at this late stage after the close of fact discovery, Amgen’s new construction, and the portions of Amgen’s expert reports that rely on that construction, should be stricken.

Respectfully submitted,

/s/ Arthur G. Connolly III

Arthur G. Connolly III

cc: Counsel of Record (via ECF)

Attachment 1

RULE 7.1.1 CERTIFICATION

I hereby certify that the subject of the foregoing motion has been discussed by telephone with counsel for Plaintiffs and that the discussion involved Delaware counsel for all parties. Despite the parties' efforts to resolve this dispute, the parties were unable to reach agreement.

/s/ Arthur G. Connolly, III

Arthur G. Connolly III (#2667)

Attachment 2

**IN THE UNITED STATES DISTRICT COURT
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MANUFACTURING, LIMITED,

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v.

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Defendants.

C.A. No. 18-1064-CFC

[PROPOSED] ORDER

WHEREAS, the Court having considered Defendants’ motion to strike portions of Plaintiffs’ infringement contentions that propose a new construction for the claim phrase “applying the refold solution to a separation matrix” in U.S. Patent No. 9,643,997 (see Exhibit 6 at 8) and to strike the portions of the expert reports of Plaintiffs’ experts Dr. Zydney and Dr. Sullivan that rely on Plaintiffs’ new construction of the “applying the refold solution to a separation matrix” phrase (see Exhibit 7 at 9, 10; Exhibit 8 at 9, 32, 52, 98, 99, 106, 109, Attachments A-4, E-4, E-5, E-6, E-7, F-1) and any opposition thereto,

IT IS HEREBY ORDERED that Defendants’ motion is GRANTED and that “applying the refold solution to a separation matrix” means “applying the refold solution to a separation matrix without intervening steps of dilution, centrifugation, dialysis, or precipitation.”

SO ORDERED this _____ day of _____, 2019.

THE HONORABLE COLM F. CONNOLLY
UNITED STATES DISTRICT COURT JUDGE

Attachment 3

**CERTIFICATION OF COMPLIANCE WITH THE NOVEMBER 6, 2019
STANDING ORDER REGARDING BRIEFING IN ALL CASES AND THE
APRIL 22, 2019 SCHEDULING ORDER FOR PATENT CASES IN WHICH
INFRINGEMENT IS ALLEGED**

I hereby certify that the text of this letter brief is in 14-point Times New Roman font and that this letter brief complies with the three-page limitation set forth in paragraph 12(a) of the April 22, 2019 Scheduling Order for Patent Cases in which Infringement Is Alleged.

/s/ Arthur G. Connolly, III
Arthur G. Connolly III (#2667)

CERTIFICATE OF SERVICE

I hereby certify that on December 3, 2019, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants. I further certify that I caused copies of the forgoing to be served on December 3, 2019 upon the following by email:

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/s/ Arthur G. Connolly, III
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